K 112292

OCT 2 1 2011

SECTION 5: 510(k) SUMMARY

Submitter:

Stryker Sustainability Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

Ramona Kulik
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Date of preparation: August 9, 2011

Name of device:

Trade/Proprietary Name: Reprocessed 2515 NAV Variable Electrophysiology Catheter
Classification Name: Electrode recording catheter or electrode recording probe

Predicate Device	510(k) Title	Manufacturer
K081258	Lasso™ 2515 NAV Variable Catheter, D-1290-01 & D-1290-02	Biosense Webster, Inc.
K082023	Reprocessed Electrophysiology Catheters	Ascent Healthcare Solutions
K031161	Lasso™ 2515 Variable Circular Mapping Catheter	Biosense Webster, Inc.

Device description:

The Reprocessed 2515 NAV Variable Electrophysiology (EP) Catheter is specially designed for electrophysiological mapping of the atria of the heart when used with the CARTO® 3 EP Navigation System and a reference device. The 2515 NAV Variable EP Catheter has platinum electrodes positioned on the distal end that can be used for stimulation and recording. The Nitinol loop design allows for the expansion and contraction of the loop to fit veins ranging from 25mm to 15mm diameter (±15%).

Indications for Use:

The Reprocessed 2515 NAV Variable EP Catheter are indicated for multiple electrode electrophysiology mapping of cardiac structures of the heart, i.e. recording or stimulation only. The Reprocessed 2515 NAV Variable EP Catheter are designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed 2515 NAV Variable EP Catheter provides location information when used with compatible CARTO® EP Navigation Systems version 1.0 or higher.

[redacted]

Technological characteristics:	The design, materials, and intended use of Reprocessed 2515 NAV Variable EP Catheter is identical to the predicate devices. The mechanism of action of Reprocessed 2515 NAV Variable EP Catheter is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of 2515 NAV Variable EP Catheter includes removal of adherent visible soil and decontamination. Each individual 2515 NAV Variable EP Catheter is tested for appropriate function of its components prior to packaging and labeling operations.
Performance data:	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed 2515 NAV Variable EP Catheter. This included the following tests: • Biocompatibility • Validation of reprocessing • Sterilization Validation • Function test(s) • Packaging Validation Performance testing demonstrates that Reprocessed 2515 NAV Variable Electrophysiology Catheter perform as originally intended.
Conclusion:	Stryker Sustainability Solutions concludes that the modified devices (Reprocessed 2515 NAV Variable Electrophysiology Catheter) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 1 2011

Stryker Sustainability Solutions
c/o Ms. Ramona Kulik
Senior Regulatory Affairs Specialist
10232 South 51st Street
Phoenix, AZ 85044

Re: K112292
Trade/Device Name: Reprocessed 2515 NAV Variable Electrophysiology Catheter (See Enclosed List of Models)
Regulatory Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II (two)
Product Code: 74 NLH
Dated: August 3, 2011
Received: August 4, 2011

Dear Ms. Kulik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K112292

Device Name: Reprocessed 2515 NAV Variable Electrophysiology Catheter

Indications For Use: The Reprocessed 2515 NAV Variable EP Catheter are indicated for multiple electrode electrophysiology mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The Reprocessed 2515 NAV Variable EP Catheter are designed to obtain electrograms in the atrial regions of the heart.

The Reprocessed 2515 NAV Variable EP Catheter provides location information when used with compatible CARTO® EP Navigation Systems version 1.0 or higher.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112292